

JONES VARGAS
300 E. Second Street, Suite 1510 - P.O. Box 281
Reno, NV 89504-0281
Tel: (775) 786-5000 Fax: (775) 786-1177

MOLLY MALONE REZAC, ESQ.
Nevada Bar No. 007435
JUSTIN J. BUSTOS, ESQ.
Nevada Bar No. 010320
JONES VARGAS
300 East Second Street
Suite 1510
Reno, NV 89501
Tel: (775) 786-5000
Fax: (775) 786-1177
E-Mail: mrezac@jonesvargas.com
jbustos@jonesvargas.com

Of Counsel:

JAMES B. MONROE, ESQ.
JUSTIN J. HASFORD, ESQ.
FINNEGAN HENDERSON FARABOW
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
Tel: (202) 408-4000
Fax: (202) 408-4400

Attorneys for Plaintiff Ferring B.V.

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

FERRING B.V.,

Plaintiff,

v.

WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC.,
WATSON LABORATORIES, INC. -
FLORIDA and WATSON PHARMA, INC.,

Defendants.

Case No.:

**COMPLAINT FOR PATENT
INFRINGEMENT**

Plaintiff Ferring B.V. ("Ferring"), by way of Complaint against Defendants Watson
Pharmaceuticals, Inc. ("Watson Pharms."), Watson Laboratories, Inc. ("Watson Labs."), Watson

1 Laboratories, Inc. - Florida (“Watson Labs. - Fla.”) and Watson Pharma, Inc. (“Watson Pharma”)
2 (collectively “Watson”), alleges as follows:

3 **THE PARTIES**

4
5 1. Ferring is a corporation organized and existing under the laws of the Netherlands
6 with its corporate headquarters at Polaris Avenue 144, 2132 JX Hoofddorp, The Netherlands.
7 Ferring is engaged in the research, development, manufacture and sale of pharmaceutical
8 products.

9 2. Upon information and belief, Watson Pharms. is a corporation organized and
10 existing under the laws of the State of Nevada, having a principal place of business at Morris
11 Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

12 3. Upon information and belief, Watson Labs. is a corporation organized and
13 existing under the laws of the State of Nevada, having a principal place of business at 311
14 Bonnie Circle, Corona, California 92880. Upon information and belief, Watson Labs. is a
15 wholly-owned subsidiary of Watson Pharms.

16 4. Upon information and belief, Watson Labs. - Fla. is a corporation organized and
17 existing under the laws of the State of Florida, having a principal place of business at 4955
18 Orange Drive, Davie, Florida 33314. Upon information and belief, Watson Labs. - Fla. is a
19 wholly-owned subsidiary of Watson Pharms.

20 5. Upon information and belief, Watson Pharma is a corporation organized and
21 existing under the laws of Delaware, having a principal place of business at Morris Corporate
22 Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief,
23 Watson Pharma is a wholly-owned subsidiary of Watson Pharms.
24
25
26

27 ///

28 ///

6. This is an action for infringement of United States Patent Number 8,022,106 (“the ’106 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Watson Labs. - Fla.’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market generic tablets containing 650 mg tranexamic acid (“Watson’s generic tranexamic acid tablets”).

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. Upon information and belief, this Court has jurisdiction over Watson Pharms.

Upon information and belief, Watson Pharms. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Watson Pharms. directly, or through its wholly-owned subsidiaries, including Watson Labs., Watson Labs. - Fla. and Watson Pharma, manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination of Watson's generic tranexamic acid tablets.

9. Upon information and belief, this Court has jurisdiction over Watson Labs. Upon information and belief, Watson Labs. directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Watson Pharms., Watson Labs. - Fla. and/or Watson Pharma, throughout the United States and in this judicial district. Upon information and belief, Watson Labs. purposefully has conducted and continues to conduct business in this judicial district.

///

JONES VARGAS
300 E. Second Street, Suite 1510 - P.O. Box 281
Reno, NV 89504-0281
Tel: (775) 786-5000 Fax: (775) 786-1177

1 10. Upon information and belief, this Court has jurisdiction over Watson Labs. - Fla.
2 Upon information and belief, Watson Labs. - Fla. directly, or indirectly, manufactures, markets
3 and sells generic drug products, including generic drug products manufactured by Watson
4 Pharms., Watson Labs. and/or Watson Pharma, throughout the United States and in this judicial
5 district. Upon information and belief, Watson Labs. - Fla. purposefully has conducted and
6 continues to conduct business in this judicial district.
7

8 11. Upon information and belief, this Court has jurisdiction over Watson Pharma.
9 Upon information and belief, Watson Pharma directly, or indirectly, manufactures, markets and
10 sells generic drug products, including generic drug products manufactured by Watson Pharms.,
11 Watson Labs. and/or Watson Labs. - Fla., throughout the United States and in this judicial
12 district. Upon information and belief, Watson Pharma purposefully has conducted and continues
13 to conduct business in this judicial district.
14

15 12. Upon information and belief, venue is proper in this judicial district under 28
16 U.S.C. §§ 1391(c) and (d), and § 1400(b).
17

18 **COUNT FOR PATENT INFRINGEMENT**

19 13. The U.S. Patent and Trademark Office (“PTO”) issued the ’106 patent on
20 September 20, 2011, and the ’106 patent expires on March 4, 2025. The ’106 patent claims,
21 *inter alia*, tranexamic acid formulations and methods of treating menorrhagia with such
22 formulations. Ferring is the owner of the ’106 patent. A copy of the ’106 patent is attached
23 hereto as **Exhibit A**.
24

25 14. Ferring Pharmaceuticals AS is the holder of New Drug Application (“NDA”) No.
26 02-2430 for tranexamic acid tablets, which the FDA approved on November 13, 2009. The ’106
27 patent is listed for NDA No. 02-2430 in the FDA’s Approved Drug Products with Therapeutic
28 Equivalence Evaluations (“the Orange Book”).

1 15. Ferring sells 650 mg dosage strengths of tranexamic acid tablets in the United
2 States under the trademark Lysteda[®].

3 16. Upon information and belief, Watson Labs. - Fla.. filed with the FDA ANDA No.
4 202093, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

5 17. Upon information and belief, Watson Labs. - Fla.'s ANDA No. 202093 seeks
6 FDA approval to sell in the United States generic tranexamic acid tablets containing 650 mg of
7 tranexamic acid intended to be generic versions of Lysteda[®].

8 18. On October 19, 2011, Ferring received a letter from Watson Labs. - Fla., dated
9 October 12, 2011, purporting to be a Notice of Certification for ANDA No. 202093 ("Watson's
10 notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21
11 C.F.R. § 314.95(c).

12 19. Watson's notice letter alleges that Watson Labs. - Fla. has submitted to the FDA
13 ANDA No. 202093 seeking FDA approval to sell in the United States generic tranexamic acid
14 tablets containing 650 mg of tranexamic acid intended to be generic versions of Lysteda[®].

15 20. Under 35 U.S.C. § 271(e)(2)(A), Watson Labs. - Fla. has infringed at least one
16 claim of the '106 patent by submitting, or causing to be submitted to the FDA, ANDA No.
17 202093 seeking approval for the commercial marketing of Watson's generic tranexamic acid
18 tablets before the expiration date of the '106 patent.

19 21. Upon information and belief, ANDA No. 202093 seeks approval of Watson's
20 generic tranexamic acid tablets that are the same, or substantially the same, as Lysteda[®].

21 22. Upon information and belief, Watson's generic tranexamic acid tablets will, if
22 approved and marketed, infringe at least one claim of the '106 patent.

23 23. Upon information and belief, Watson Labs. - Fla. will, through the manufacture,
24 use, import, offer for sale and/or sale of Watson's generic tranexamic acid tablets, directly
25
26
27
28

1 infringe, contributorily infringe and/or induce infringement of at least one claim of the '106
2 patent.

3 24. Upon information and belief, Watson Labs. - Fla.'s actions relating to ANDA No.
4 202093 complained of herein were done with the cooperation, the participation, the assistance of,
5 and at least in part for the benefit of, Watson Pharms., Watson Labs. and Watson Pharma.
6

7 **WHEREFORE**, Plaintiff Ferring respectfully requests that the Court enter judgment in
8 its favor and against Defendants Watson Pharms., Watson Labs., Watson Labs. - Fla. and Watson
9 Pharma on the patent infringement claims set forth above and respectfully requests that this
10 Court:
11

- 12 1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Watson has infringed at least
13 one claim of the '106 patent through Watson Labs. - Fla.'s submission of ANDA
14 No. 202093 to the FDA to obtain approval for the commercial manufacture, use,
15 import, offer for sale and/or sale in the United States of Watson's generic
16 tranexamic acid tablets before the expiration of the '106 patent;
- 17 2) order that the effective date of any approval by the FDA of Watson's generic
18 tranexamic acid tablets be a date that is not earlier than the expiration of the '106
19 patent, or such later date as the Court may determine;
- 20 3) enjoin Watson from the commercial manufacture, use, import, offer for sale
21 and/or sale of Watson's generic tranexamic acid tablets until the expiration of the
22 '106 patent, or such later date as the Court may determine;
- 23 4) enjoin Watson and all persons acting in concert with Watson from seeking,
24 obtaining or maintaining approval of Watson Labs. - Fla.'s ANDA No. 202093
25 until the expiration of the '106 patent;
26
27
28

///

- 1 5) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and
2 award Ferring costs, expenses and disbursements in this action, including
3 reasonable attorneys fees; and
4
5 6) award Ferring such further and additional relief as this Court deems just and
6 proper.

7 DATED this 25th day of November, 2011.

8 JONES VARGAS

9 /s/ Molly Malone Rezac
10 MOLLY MALONE REZAC, ESQ.
11 JUSTIN J. BUSTOS, ESQ.
12 300 East Second Street, Suite 1510
13 Reno, NV 89501
14 Tel: (775) 786-5000
15 Fax: (775) 786-1177

16 ***Of Counsel:***

17 JAMES B. MONROE, ESQ.
18 JUSTIN J. HASFORD, ESQ.
19 FINNEGAN HENDERSON FARABOW
20 GARRETT & DUNNER, LLP
21 901 New York Avenue, NW
22 Washington, DC 20001-4413
23 Tel: (202) 408-4000
24 Fax: (202) 408-4400

25 *Attorneys for Plaintiff Ferring B.V.*
26
27
28

JONES VARGAS
300 E. Second Street, Suite 1510 - P.O. Box 281
Reno, NV 89504-0281
Tel: (775) 786-5000 Fax: (775) 786-1177

TABLE OF EXHIBITS

Exhibit	Exhibit Description	Pages ¹
A	Copy of the '106 patent	54

JONES VARGAS
300 E. Second Street, Suite 1510 - P.O. Box 281
Reno, NV 89504-0281
Tel: (775) 786-5000 Fax: (775) 786-1177

¹ Exhibit page count is exclusive of exhibit slip sheets.